DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

3-9-2004

Kema Quality B.V.
c/o Merit Medical Systems, Inc.
Mr. J.A. van Vugt
N.V. KEMA
Utrechtseweg 310
NL-6812 AR Arnhem
The Netherlands

Re: K040138
Trade/Device Name: Viceroy Inflation Device
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: MAV
Dated: January 21, 2004
Received: January 22, 2004

Dear Mr. Vugt:

This letter corrects our substantially equivalent letter of February 13, 2004 regarding the address change.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K040138

FEB 13 2004

Merit Medical Systems, Inc.
Viceroy™ Inflation Device
PREMARKET NOTIFICATION [510(k)]

SECTION E

510(k) Summary

Submitter's Information:

Merit Medical Systems, Inc.
1600 W. Merit Parkway
South Jordan, UT 84095
Phone - 801-253-1600
FAX - 801-253-6911
Primary Contact: John Nicholson
Alternate Contact: Ms. Jerrie Hendrickson
Preparation Date: December 17, 2003

Device Information

Trade Name: *Viceroy* Inflation Device
Common Name: Inflation Device
Classification Name: Angiographic Injector and Syringe
Classification Number: 21CFR, Part 870.1650 - Class II

Predicate Device(s):

- Boston Scientific's LeVeen™ Inflator Disposable Inflation Syringe
- Guidant's Indeflator™ 20/30 Inflation Device
- Wilson-Cook's Quantum™ Inflation Device

Device Description:

The *Viceroy* Inflation Device is a manually-controlled inflation device clinicians use to inflate and deflate an angioplasty balloon. The device is composed of a handle or knob which the clinician manipulates to achieve the desired pressure. The handle is connected to a threaded plunger which provides for incremental pressure regulation of the syringe barrel. A locking mechanism is incorporated to maintain a constant pressure without direct user effort. The syringe barrel allows for the storage of desired pressurization rates and its walls are transparent for syringe barrel content visualization. In most *Viceroy* configurations an analog gauge is available for measuring barrel pressure and the gauged devices are connected to high pressure tubing which terminates in a rotating male luer lock connector. The non-gauged devices also terminate in a rotating male luer lock connector.

K040138

Merit Medical Systems, Inc.
Viceroy™ Inflation Device
PREMARKET NOTIFICATION [510(k)]

Intended Use:	The *Viceroy* Inflation Device is intended to inflate and deflate an angioplasty balloon or other interventional device and when equipped with a gauge, to monitor the pressure within the balloon.
Technological Characteristics:	Both the predicate and applicant devices achieve equivalent clinical functions by utilizing comparable device designs and biocompatible materials to inflate and deflate an angioplasty balloon or other interventional device and to monitor the pressure within the balloon.
Non-Clinical Testing:	Merit has performed a series of comparative mechanical tests to support a substantially equivalent determination and to demonstrate the device's safe and effective performance when used as intended. The performance data indicate that the applicant and the predicate devices have substantially equivalent values. They also indicate that the design of the applicant device is sufficiently robust for its intended use. There are no new safety and efficacy questions which arise when the applicant device is used as intended.
Conclusion:	The *Viceroy* Inflation Device has met all acceptance criteria. Based upon FDA's substantial equivalence criteria, the Viceroy Inflation Device has been demonstrated to be substantially equivalent to the cited predicate devices based on intended use, labeling, design, materials, pressurization ranges and comparative performance.

Indications for Use

510(k) Number (if known): K040138

Device Name: Viceroy Inflation Device

Indications For Use: To inflate and deflate an angioplasty balloon or other interventional device and when equipped with a gauge, to monitor the pressure within the balloon.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040138